REMARKS

Upon entry of the present amendment, claims 1 and 6-11 will remain pending in the above-identified application and stand ready for further action on the merits.

The amendments made herein to the claims do not incorporate new matter into the application as originally filed. In support of this contention, the following is noted.

First, support for the amendment to claim 1 as well as newly added claim 6, occurs at page 15, lines 18-21 of the specification, which describes that "The formulation of the present invention can be prepared, for example, by mixing … before curing;", and on page 16, line 9, which describes "curing method is …".

Regarding newly added claim 7, the same finds support at page 15, lines 2-6, which describes "Shape of the formulation of the present invention …, particularly, include cylindrical, prismatically cylindrical, cylindroid, tabular, and spherical shape".

Support for newly added claims 8-11 occurs in original claims 2-5, now cancelled. In this respect, claims 8-11 are based upon original claims 2-5, but their dependencies have been corrected to reflect, for example, the existence of new claims 6-7.

Abstract

The Abstract of the Disclosure is objected to allegedly because the application did not contain an Abstract of the Disclosure on a separate sheet. This is incorrect. The original application contained twenty-six (26) sheets with page 26 being an abstract. Accordingly, enclosed herewith is a copy of the original abstract filed with the present application on April 3, 2002.

Claim Rejections Under 35 USC § 103

Claims 1-3 have been rejected under 35 USC § 103(a) as being unpatentable over Dunn et al. (US 5,324,519). Further, claims 1-5 have been rejected under 35 USC § 103(a) as being unpatentable over Fujioka et al. (US 4,985,253) and Dunn et al. (US 5,324,519). Reconsideration and withdrawal of each of these rejections is respectfully requested based upon the following considerations.

Dunn et al. (US 5,324,519)

Dunn describes at line 11, in column 2, that "The composition is a liquid formulation", showing explicitly that the composition is in a liquid form.

On the other hand, claim 1 of the present application has been amended to direct to a solid formulation for implantation, which is different from the invention of Dunn. As well, the inventions of

new claims 6 and 7, and the dependent claims therefrom are also different from the invention of Dunn.

As the Examiner pointed out, the abstract of Dunn recites the word "solid". However, the word qualifies a "matrix", which should be made as a result of a pore formation by a pore-forming agent, and does not qualify the "composition" itself of the intended invention of Dunn.

In order to show the unobviousness of the present invention, the following comments are provided to emphasize differences between the liquid formulations of Dunn and the solid formulations of the instant invention.

As the Examiner may have noticed, a liquid formulation of Dunn is formed into polymer matrices having pores in them (see column 3, lines 11 to 55). Dunn describes the preparation of polymer matrices having pores in them, which comprises using a carbonate as one of the preparations. It should be noted that, in Dunn, a carbonate is used to generate pores within the polymer matrices to be formed, and therefore the liquid form is necessary in order for a carbonate to sufficiently contact with the water existing in an ambient atmosphere.

If a carbonate is comprised in the formulation of Dunn and the formulation is made to be a solid, then the contact between the carbonate and the water in an ambient atmosphere is limited, and therefore the pore formulation by the carbonate is less effective.

Accordingly, Dunn does not teach the present invention, and instead rather teaches away from the present invention.

On the other hand, a carbonate comprised in a solid formulation according to the present invention produces a physical protruding force derived from the inside of the formulation, not by forming pores as occurs in Dunn.

As shown above, the role of a carbonate is different between the liquid formulation of Dunn and the solid formulation of the present invention, which constitutes a different technical solution, although a carbonate may be comprised both in the solid formulation of the present invention and the liquid formulation of Dunn.

Fujioka et al. (US 4,985,253)

As discussed above, Dunn describes a liquid formulation, whereas Fujioka describes a solid formulation. Accordingly, the combination of Dunn and Fujioka is not an appropriate combination to deny the unobviousness of the present invention.

Further, Fuijoka fails to describe any solid formulation comprising a carbonate. Accordingly, there is no motivation to combine Dunn and Fujioka, as the role of a carbonate in the solid formulation according to the present invention would not be derived from the combination. Rather, the disclosure in Dunn teaches a

person skilled in the art away from combining Dunn and Fujioka as explained above when discussing Dunn.

Unexpected Results

Additionally, the present invention has unexpected results when compared with the possible combination of Dunn and Fujioka as shown below.

Vaccine as described in Dunn comprises bacterial components, which are usually insoluble in body fluid or water. When incorporated into formulations intended to be sustained-release, such components are released in an extremely slow manner as shown from line 21 on page 1 through line 20 on page 2 in the specification of the present application. That problem has been solved for the first time by the solid formulation of the present invention, wherein the force of the carbon dioxide gas generated internally by the reaction of carbonate and the body fluid acts to protrude an active ingredient comprised in the formulation toward the outside of the formulation, and thereby accelerates the release of it.

Specifically, Table 1 on page 20 in the present specification shows that formulations 1 and 2 according to the present invention released latex beads, as a model of an insoluble active ingredient, at more than 30 μg/ml for 15 days, whereas reference formulation 2 (glycine-containing silicone formulation: Reference 2 on page 19 in

the present specification) released latex beads merely at 0.1 μg/ml. Reference formulation 2 is regarded as being similar to the formulation of Fujioka because reference formulation 2 comprises glycine, which is believed to function to accelerate the release of the active ingredient in a similar manner to albumin that is contained in the formulation of Fujioka. Thus, Table 1 in the present specification demonstrates that the formulation of the present invention accelerates the release of an active ingredient more than 300 times when compared to formulations like those of Fujioka, which is a completely unexpected result.

Accordingly, the combination of Dunn and Fujioka does not lead one of ordinary skill in the art to the present invention, or provide any motivation to arrive at the same or the unexpected results that are possessed thereby.

Provisional Request for Interview

Should the present response, including the amendments and remarks presented herein, not place the application in condition for allowance, the Examiner is respectfully requested to contact the undersigned to schedule a personal interview with the Examiner at the Examiner's earliest convenience. It is believed that such an interview would be helpful to forward prosecution of this application towards allowance, should the Examiner not deem that all claims pending are now allowable.

CONCLUSION

Based upon the amendments and remarks presented here, the Examiner is respectfully requested to issue a Notice of Allowance clearly indicating that each of pending claims 1 and 6-11 are allowable at present.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact John W. Bailey (Reg. No. 32,881) at the telephone number below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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By _____
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JWB:enm
0020-4976P

Attachment: Abstract of the Disclosure